DICLOFENAC SODIUM TOPICAL GEL, 1%- diclofenac sodium topical gel, 1% (nsaid) gel
Mohnark Pharmaceuticals Inc.

Diclofenac Sodium 1% Topical Arthritis Gel

ACTIVE INGREDIENT

Diclofenac sodium (NSAID*) 1%
*nonsteroidal anti-inflammatory drug

INACTIVE INGREDIENTS

Inactive ingredients:

Carbomer Homopolymer Type C, Coco-Caprylate/caprate, Isopropyl Alcohol, Mineral Oil, Polyoxyl 20 Cetostearyl Ether, Propylene Glycol, Purified Water, Strong Ammonia Solution

PURPOSE

Arthritis pain reliever

USES

for the temporary relief of arthritis pain ONLY in the following areas:
- hand, wrist, elbow (upper body areas)
- foot, ankle, knee (lower body areas)

this product may take up to 7 days to work for arthritis pain; it is not for immediate relief. If no pain relief in 7 days, stop use

WARNINGS

For external use only

Allergy alert: Diclofenac may cause a severe allergic reaction, especially in people allergic to aspirin.

Symptoms may include:

• hives • asthma (wheezing) • skin reddening • blisters • facial swelling • shock • rash

If an allergic reaction occurs, stop use and seek medical help right away.

Liver warning: This product contains diclofenac. Liver damage may occur if you apply
- more or for a longer time than directed
- when using other drugs containing diclofenac

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is small but higher if you
- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- apply more or for longer than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

DO NOT USE

- if you have ever had an allergic reaction to any other pain reliever or to a fever reducer
- for strains, sprains, bruises or sports injuries. This product has not been shown to work for these types of

injuries.
- right before or after heart surgery
- on more than 2 body areas at the same time
- in the eyes, nose or mouth

ASK A DOCTOR BEFORE USE IF

- you have problems or serious side effects from taking pain relievers or fever reducers
- stomach bleeding warning applies to you you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you are under age 18 years. It is not known if this drug works or is safe in children under age 18 years.

ASK A DOCTOR OR PHARMACIST BEFORE USE IF YOU ARE

- under a doctor’s care for any serious condition
- taking any other drug

WHEN USING THIS PRODUCT

- avoid contact with eyes, nose, or mouth
- if eye contact occurs, rinse thoroughly with water

STOP USE AND ASK A DOCTOR IF

- pain gets worse or lasts more than 21 days
- redness or swelling is present in the painful area
- fever occurs
- skin irritation occurs
- any new symptoms appear. These could be signs of a serious condition.
- you experience any of the following signs of stomach bleeding
- feel faint
- have bloody or black stools
- vomit blood
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke
- chest pain
- trouble breathing
- leg swelling
- weakness in one part or side of body
- slurred speech

IF PREGNANT OR BREAST-FEEDING

ask a health professional before use. It is especially important not to use this product during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS

Use up to 21 days unless directed by your doctor

Not for strains, sprains, bruises or sports injuries. This product has not been shown to work for these types of injuries.

For your arthritis pain:Daily Per Dose

Use 4 times per day every day
Do not use on more than 2 body

areas at the same time

Use DOSING GUIDE to measure a dose

For each upper body area (hand, wrist, or elbow)

- Squeeze out 2.25 inches (2 grams)

For each lower body area (foor, ankle or knee) -

Squeeze out 4.5 inches (4 grams)

Read the entire directions on carton for instructions:

use only as directed
do not use more than directed or for longer than directed
apply only to clean, dry skin that does not have any cuts, open wounds, infections or rashes
do not apply in same area as any other product
do not apply with external heat such as heating pad
do not apply a bandage over the treated area

store Diclofenac Sodium Gel with carton and dosing guide as shown.

OTHER INFORMATION

- Store at 20-25°C (68°F - 77°F). Keep from freezing.
- read all product information before using. Keep from freezing. read all product information before using. Keep this carton for important information.

Inactive ingredients

Carbomer homopolymer Type C, cocoyl caprylocaprate, ispropyl alcohol, mineral oil, polyoxyl 20 cetostearyl ether, propylene glycol, purified water, strong ammonia solution.

Question and comments: 1-866-611-5206

INDICATIONS AND USAGE

Diclofenac is a nonsteroidal anti-inflammatory drug (NSAID). This medicine works by reducing substances in the body that cause pain and inflammation.

Diclofenac is used to treat mild to moderate pain, or signs and symptoms of osteoarthritis or rheumatoid arthritis.

PRINCIPAL DISPLAY PANEL

Carton Label - NDC 73715-005-01

Diclofenac Sodium Topical Gel, 1%

(NSAID)- Arthritis pain reliever

For external use only

For daily Treatment of Arthritis Pain Anti-Inflammatory

Net Wt 1.76 oz (50g)

DICLOFENAC SODIUM TOPICAL GEL, 1%
diclofenac sodium topical gel, 1% (nsaid) gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73715-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DICLOFENAC SODIUM (UNII: QTG126297Q) (DICLOFENAC - UNII:144O8QL0L1)	DICLOFENAC SODIUM	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73715-005-01	50 g in 1 CARTON; Type 0: Not a Combination Product	08/31/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210986	08/31/2021	

Labeler - Mohnark Pharmaceuticals Inc. (117013830)

Registrant - Mohnark Pharmaceuticals Inc. (117013830)

Establishment

Name	Address	ID/FEI	Business Operations
Mohnark Pharmaceuticals Inc		117013830	manufacture(73715-005)

Revised: 4/2021 Mohnark Pharmaceuticals Inc.